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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,158

10/13/2005

Symon D'Oyly Cotton

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OLIFF & BERRIDGE, PLC

P.O. BOX 320850

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

NOTIFICATION DATE

DELIVERY MODE

07/23/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com

jarmstrong@oliff.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,158	<b>Applicant(s)</b> COTTON ET AL.	
	<b>Examiner</b> KATHERINE L. FERNANDEZ	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-63 is/are allowed.
- 6) ☒ Claim(s) 1-44 and 64-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/5/05; 2/16/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

***Claim Objections***

1. Claims 24-25 are objected to because of the following informalities:

Claim 24 recites the limitation "the predetermined wavebands", "the three wavebands" and "the two ratios" in lines 1-2. There is insufficient antecedent basis for these limitations in the claim.

Claim 25 recites the limitation "the predetermined wavebands" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Further, in line 4, the phrase "the or" should be deleted.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regards to claim 4, in lines 6-7, it is unclear as to whether the first and second wavebands refer to the wavebands of the illuminated light or the wavebands of the remitted light.

4. Claims 17 and 19-22 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

With regards to claim 17 and 19-22, the claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be

Art Unit: 3768

organized and correlated in such a manner as to present a complete operative device.

The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

***Claim Rejections - 35 USC § 101***

Claims 1-25, 33-44 and 64-74 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

With regards to claims 1-25,33-44 and 64-74, in addition to inquiry of whether a claimed method fails within a judicial exception, the Supreme Court has decided in *Bilski v. Kappos* that under its precedents (*Benson*, *Flook*, *Diehr*), the claims in *Bilski* are not patent-eligible processes under section 101 because they are an attempt to patent abstract ideas. Thus, claims drawn to a process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (i.e. meet the machine-or-transformation test). If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. 101 and is improperly directed to nonstatutory subject matter. To qualify as a 101 statutory process, the claim should (1) positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps or (2) positively recite the subject matter that is being transformed. The limitations (i.e. illuminating and receiving light, analyzing the received light, defining potential wavebands and image ratios, obtaining a function, etc.) are non-statutory because they are not tied to another statutory class (such as a particular apparatus), nor do they

Art Unit: 3768

positively recite subject matter being transformed, and thus they do not meet the machine-or-transformation test.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cotton (WO 98/22023) as cited by Applicant.

Cotton discloses a method and apparatus of analyzing at least one parameter of a body component, comprising the steps of illuminating the component or body with light of at least a first and second wavelength (pg. 4, entire page; pg. 14, 2nd paragraph), receiving light of at least said first and second wavebands remitted by the component at a photoreceptor or photoreceptors (pg. 4, entire page; pg. 14, 2nd paragraph), and analyzing the light received at the photoreceptor(s) to provide a ratio between the amount of light remitted of the first waveband and the amount of light remitted of the second waveband, and from this calculating the component parameter (pg. 4, entire page; pg. 14, 2<sup>nd</sup> paragraph; see Figure 1, note that the slope is equal to a ratio between the amount of light remitted of the first waveband and the amount of light remitted of the second waveband). With regards to claims 2 and 3, the wavebands are predetermined and calculated/derived by use of a mathematical/biological model of the body component and its characterizing parameters (pg. 4, entire page, note that the two

Art Unit: 3768

wavebands are chosen such that the absorption of blood within these wavelengths is very small).

7. Claims 1-11,14-17,19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Koenig et al. (US Patent No. 6,289,236).

Koenig et al. disclose a method of analyzing at least one parameter of a body component (i.e. human or animal tissue, such as skin, epithelial tissue,etc.), comprising the steps of illuminating the component or body with light of at least a first and second waveband (column 2, lines 18-34), receiving light of at least said first and second wavebands remitted by the component at a photoreceptor or photoreceptor(s), but eliminating light reflected by the component or body (column 2, lines 18-34; column 3, line 64-column 4, line 36), and analyzing the light received at the photoreceptor(s) to provide a ratio between the amount of light remitted of the first waveband and the amount of light remitted of the second waveband, and from this calculating the component parameter (column 2, lines 18-34). With regards to claims 2-3, the wavebands are predetermined and calculated/derived by use of a mathematical/biological model of the body component and its characterizing parameters (column 3, lines 26-61). With regards to claims 6-8 and 20-22, the waveband ratios are compared with a mathematically generated/experimentally measured model of waveband ratios corresponding to a range of component parameters and the comparison results in a measure or measures relating to the component parameter or parameters (column 2, lines 18-34). With regards to claim 9, a function is derived relating the computed ratios and the component parameter or parameters (column 2,

Art Unit: 3768

lines 18-34). With regards to claims 10 and 14, the light reflected by the component is eliminated by the use of a pair of cross polarized linear polarizing filters, one filter being placed between the source of illumination and the component, and the other filter placed between the component and the photoreceptor or photoreceptors (column 3, line 65-column 4, line 36). With regards to claim 11, the light illuminating the body component is a light of a plurality of wavelengths which includes at least the wavebands (column 3, line 65-column 4, line 36).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4,6-9,11,14-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotton in view of Kaminski et al. (US Patent No. 5,640,957).

Cotton discloses a method of analyzing at least one parameter of a body component, comprising the steps of illuminating the component or body with light of at least a first and second wavelength (pg. 4, entire page; pg. 14, 2nd paragraph), receiving light of at least said first and second wavebands remitted by the component at a photoreceptor or photoreceptors (pg. 4, entire page; pg. 14, 2nd paragraph), and analyzing the light received at the photoreceptor(s) to provide a ratio between the amount of light remitted of the first waveband and the amount of light remitted of the second waveband, and from this calculating the component parameter (pg. 4, entire

Art Unit: 3768

page; pg. 14, 2<sup>nd</sup> paragraph; see Figure 1, note that the slope is equal to a ratio between the amount of light remitted of the first waveband and the amount of light remitted of the second waveband). With regards to claims 6-8 and 20-22, the waveband ratios are compared with a mathematically generated/experimentally measured model of waveband ratios corresponding to a range of component parameters and the comparison results in a measure or measures relating to the component parameter or parameters (pg. 10, last paragraph-pg. 12, 2<sup>nd</sup> paragraph; pg. 15, 3<sup>rd</sup> paragraph). With regards to claims 9 and 22, a function is derived relating the computed ratios and the component parameter or parameters (pg. 7, last paragraph-pg. 10, 2<sup>nd</sup> paragraph; pg 15, 3<sup>rd</sup> paragraph). With regards to claim 11, the light illuminating the body component is a light of a plurality of wavelengths which includes at least the wavebands (pg. 14, 2<sup>nd</sup> paragraph; pg. 4, entire page). With regards to claim 14, at least one filter is placed sequentially between the source of illumination and the component or between the component and the photoreceptor or photoreceptors (pg. 4, entire page). With regards to claims 15-16, the body component is human or animal tissue, such as skin (pg. 1, 1<sup>st</sup> paragraph). With regards to claim 23, the body component is skin and the parameters are the concentration of melanin and the concentration of blood (pg. 6, 1<sup>st</sup> full paragraph).

Although Cotton et al. disclose that their invention is interested in the interior layers of the skin (i.e. dermis layer), they do not specifically disclose that light reflected by the component or body is eliminated.



Kaminski et al. disclose an ultraviolet radiation protection evaluator (column 2, lines 5-10). They disclose that their invention is interested in the transmission/reflection of light in the deeper layers of skin, and therefore radiation that reflects from the surface is noise, and thus their invention is configured to not receive light corresponding to ambient and other noise effects such as radiation reflected and diffused from the surface of skin (column 4, lines 26-38; column 5, lines 19-37). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Cotton to have the light reflected by the component or body be eliminated, as taught by Kaminski, as light reflected from the surface is considered as noise since their invention is interested in evaluating the reflection from the interior layers of the component/body (column 4, lines 26-38, column 5, lines 19-37).

10. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koenig et al. as applied to claim 11.

As discussed above, Koenig et al. meet the limitations of claim 11. With regards to claim 12-13, although Koenig et al. do not specifically disclose the illuminating light is ambient light or sunlight, they do disclose that the wavebands fall within the ambient light or sunlight wavelength range, and therefore, it would have been obvious to one of ordinary skill in the art to have the illuminating light be ambient light or sunlight as these illumination sources are capable of providing the desired wavebands.

***Allowable Subject Matter***

11. Claims 45-63 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest a concentration determination module operable to determine for positions within an image represented by generated image data the concentrations of chromophores and/or thickness of structural layers of said epithelial tissue at said positions in the sample of epithelial tissue represented by said image data utilizing said first and said second ratios determined for said positions by said ratio determination module in combination with the other claimed elements.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cotton et al. and Koenig et al. disclose a method of analyzing at least one parameter of a body component using first and second wavebands, providing a ratio of remitted light and using the ratio to calculate the component parameter, but they do not teach or suggest calculating predetermined wavebands such that the component parameter is a one to one function of the ratio between the amount of light remitted by the component of the first predetermined waveband of the pair and the amount of light remitted by the component of the second predetermined waveband of the pair.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

Art Unit: 3768

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768